IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

IN RE:	§	
	§	
PREMPRO PRODUCTS LIABILITY LITIGATION	§	MDL Docket No. 4:03CV1507-WRW
	§	
	§	
IRENE ANDERSON and KENNETH ANDERSON,	§	Case No. 4:05-CV-01246-WRW
	§	
	§	
Plaintiffs,	§	
	§	
VS.	§	
	§	
BARR LABORATORIES, INC.	§	
	§	
Defendant.	§	

PLAINTIFF'S THIRD AMENDED COMPLAINT

COME NOW Irene Anderson and Kenneth Anderson ("Plaintiffs") complaining of Defendant Barr Laboratories, Inc., ("Barr"), and would respectfully show the Court as follows:

I. INTRODUCTION

1.01 Plaintiff Irene Anderson is a consumer of hormone replacement therapy drugs, who has been injured as a result. Plaintiffs now brings suit, and the suit has already been consolidated into the Multi District Litigation, Docket No. 4:03-CV-1507-WRW ("MDL"), currently pending in the Eastern District of Arkansas, Western Division.

II. JURISDICTION AND VENUE

2.01 This Court has jurisdiction over the non-resident Defendants because each has done business in the State of California, has committed a tort in whole or in part in the State of California, and has continuing contacts with the State of California.

2.02 Venue of this case is proper in the Northern District of California because all of the Defendants market and sell drugs there. This case has already been consolidated into the MDL situated in the Eastern District of Arkansas, Western Division. At the conclusion of the MDL, venue would be properly remanded to the Northern District of California, as all of the Defendants market and sell drugs there.

2.03 Plaintiffs' damages are in excess of the minimum jurisdictional limits of the Court.

III. PARTIES

3.01 Irene Anderson and Kenneth Anderson are citizens of California and residents of Marin County, California.

3.02 Defendant Barr Laboratories, Inc. is a Delaware corporation with its principal place of business in Pomona, New York. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including the hormone therapy drug medroxyprogesterone acetate (MPA), the generic equivalent of Upjohn's drug Provera. In 2001, defendant Barr acquired and merged with Duramed. As the successor in interest of Duramed,

defendant Barr has assumed all tort liabilities for Duramed's drugs. Plaintiffs refer to defendant Barr Laboratories, Inc. as "Barr." Defendant Barr has already answered and appeared herein.

IV. FACTS

A. Plaintiff Acquired Breast Cancer after Ingesting Hormone Replacement Drugs

4.01 Irene Anderson began hormone replacement therapy in 1996 and discontinued that treatment in 2002 when she was diagnosed with breast cancer. A biopsy confirmed infiltrating ductal carcinoma of the left breast, with positive estrogen and progesterone receptors. She underwent a lumpectomy and radiation therapy, and her condition remains guarded.

4.02 Irene Anderson was prescribed defendant Barr's Estradiol from 1999 to 2002 and Barr's MPA from 1996 to 2002.

B. The Creation of A Disease

4.02 In 1942, Ayerst (the predecessor to Wyeth and Wyeth Pharmaceuticals) received approval to manufacture and market Premarin, a conjugated equine estrogen made from the urine of pregnant horses. Premarin has remained chemically unchanged from 1942 up until this day, and has been marketed as a hormone replacement product to replace the natural human female hormone, estrogen.

4.03 Since 1942, Wyeth (and later the Defendants) has continuously and vigorously promoted its menopausal hormone therapy products using a variety of marketing messages that emphasize the use of these medications for long-term relief of menopause symptoms. The marketing logo in the early to mid 1970's describes Premarin as a medication to "start her on, keep her on." Even in the early 1990's, Wyeth continued to market its hormone therapy product as medicines that required continued use – "protection continued only as long as estrogen therapy continued." The

Defendant joined in this marketing and advertising scheme, to a lesser extent. To distribute this message to both patients and doctors, a number of different marketing methods were used:

1. Sponsoring medical journal articles about the benefits of their products, oftentimes with questionable results drawn from doubtful scientific principles;

2. Sales representatives and "detail persons" calling on and encouraging physicians to prescribe these drugs;

3. Sponsoring continuing medical education programs to discuss the purported benefits of these products, often without appropriate description of the corresponding risks;

4. Hiring physicians in the field to speak to other physicians as an effort to market these medicines;

5. Press releases of audio, written, and television advertising;

6. Direct-to-consumer advertising in addition to physician-directed advertising;

7. Medical journal and consumer journal advertising materials; and

8. Sponsoring medical and pseudo-medical organizations to provide "approval" or sponsoring support for the use of these products.

4.04 These different message delivery systems were intended to be twofold: first to create the "disease" of menopause and thereafter to market the "solution" of hormone replacement drugs.

4.05 In 1977, the Food & Drug Administration issued a statement confirming that estrogen therapy should not be used to treat nervousness during menopause, and that there was no scientific support or any representation that estrogen could keep a woman feeling young or keep her skin soft. By the time of these reports, Premarin was the fifth most frequently prescribed drug in the United States.

4.06 The first truly scientific literature was published in 1975 in the *New England Journal of Medicine*. Two articles appeared that linked estrogen therapy to a significantly increased risk of women developing endometrial cancer. Estrogen sales plummeted, and the drug companies were in search of a resurrection for their miracle pill.

4.07 In 1979, that miracle appeared in the form of an article written by Dr. Robert Greenblatt published in the *Journal of Geriatrics Society*. Dr. Greenblatt proposed that estrogen-related uterine cancer could be avoided if progesterone was added to the estrogen regimen. Immediately, Wyeth and the others began promoting this combination hormone therapy – Premarin with Provera as a hormone therapy combination. Pfizer, as the manufacturer of Provera, was delighted to join the "bandwagon."

4.08 Once again, Dr. Greenblatt's proposed remedy was bereft of scientific support, and there was no published scientific literature to even discuss the issue until the Women's Health Initiative was begun in the late 1990's.

4.09 By the mid 1990's, various governmental agencies began questioning the appropriateness of advertising estrogen and hormone replacement therapy as "cures" for all these various conditions caused by the "disease" of menopause. Seeking FDA approval for the use of these different medicines to "cure" these conditions, Wyeth agreed to participate in and sponsor various studies.

4.10 One of these studies (Heart and Estrogen/Progestin Replacement Study) was conducted in order to confirm that estrogen/progestin combination therapy did in fact reduce the risk of heart disease. This study began in 1994. The results of the study were published in 1998, when the investigators reported that hormone therapy did not reduce the rate of coronary heart disease, and in fact dramatically increased the risk of heart disease and heart attack in these women.

4.11 The manufacturers immediately began distancing themselves from and minimizing the results of the HERS study.

4.12 The second study, called the Women's Health Initiative, also began in the early 1990's. This study was conducted by the National Institute of Health and was designed to

definitively answer questions about estrogen/progestin therapy's benefits for heart health, osteoporosis and the other menopausal symptoms identified in advertising.

4.13 The Women's Health Initiative was intended to run for 15 years; however, the National Institute of Health halted this study prematurely because the risks of taking hormone replacement therapy outweighed any potential benefits. The study concluded that "overall health risks exceeded benefits from use of combined estrogen plus progestin ..."

4.14 Under California law, a manufacturer is held to the knowledge and skill of an expert in the field. A manufacturer is obligated to keep abreast of any scientific discoveries and is presumed to know the results of all such advances. A manufacturer cannot defeat liability because it did not review the relevant scientific literature. This duty of expertise made each defendant responsible not only for actual knowledge gained from research and adverse reaction reports, but also for constructive knowledge as measured by scientific literature and other available means of communication. A manufacturer may also be liable under negligence for failure to warn of a risk that was subsequently discovered and/or for failure to undertake sufficient testing before distribution. During the time plaintiff ingested defendants' HRT drugs, each defendant knew or reasonably should have known, as experts of their products, of the potential association between combination HRT and breast cancer. Each defendant also knew or should have known that synthetic MPA was far more potent and potentially carcinogenic to the breast than progesterone. Despite this knowledge, each defendant manufactured, marketed and sold its HRT products to unwary women for the treatment of menopausal symptoms.

4.15 In 2000, the FDA notified all manufacturers of hormone replacement therapy (HRT) drugs, including Barr, Barr's predecessor in interest, Duramed, and Upjohn, that they should insert class-wide labeling in their drugs' physician package insert to warn that the risk of breast cancer was

higher in HRT containing both estrogen and progestins than it was in estrogen alone. Defendant Barr and Upjohn did not add this class labeling to their package inserts. Their failure to do so violated the safety provisions of the federal Food, Drug and Cosmetic Act. Plaintiff would have avoided injury from breast cancer, or she would have reduced her risk of developing breast cancer, had defendant Barr adequately warned the medical profession in its MPA package insert by inserting the class labeling language, as directed by the FDA, concerning the heightened breast cancer risk posed by the addition of MPA to estrogen in HRT.

V. CAUSES OF ACTION

A. Negligence

5.01 Defendant Barr manufactured, marketed, promoted and sold its drug MPA to plaintiff and her physician from 1999 to 2000.

5.02 Defendant had a duty of care under California law to undertake reasonable measures to market a safe product. This duty also included knowing the potential risks of MPA when marketed for foreseeable uses.

5.03 Combination use with estrogen in HRT to treat symptoms of menopause was a known, intended and foreseeable use of defendant's drug MPA. Nearly all of defendant's profits from the sale of MPA during the relevant time period derived from combination estrogen + MPA prescriptions.

5.04 Defendant breached its duties of care, and was therefore negligent, in the following particulars:

a) Defendant manufactured, marketed, promoted, and sold its drug MPA for use as combination HRT despite knowing that this combination had been shown in published studies to increase the risk of breast cancer;

b) Defendant manufactured, marketed, promoted, and sold its drug MPA for use in combination HRT despite knowing that the safety of MPA in combination with estrogen for the treatment of menopausal symptoms had not been adequately established;

c) In 2000 and thereafter, defendant failed to update the package insert for MPA to include new class labeling regarding breast cancer risk, as the FDA instructed defendant and all other HRT manufacturers to do. The FDA's new language to be inserted in all HRT labels warned that the addition of synthetic progestins, including MPA, to estrogen for HRT poses a higher risk of breast cancer than estrogen alone. Defendant's failure to strengthen its label to include these class-wide warnings was a violation of its duty of care under California law. No federal statute or regulation prohibited defendant from adopting the FDA-imposed class labeling for all HRT products.

d) In 2000 and thereafter, defendant failed to send "dear doctor" letters notifying physicians of the FDA's new class labeling for all HRT products, which warned that the addition of synthetic progestins, including MPA, to estrogen for HRT poses a higher risk of breast cancer than estrogen alone. Defendant's failure to notify physicians in this manner was a violation of its duty of care under California law. No federal statute or regulation prohibited defendant from conveying this information to physicians in the form of a "dear doctor" letter or similar communication.

5.05 Defendant's negligence was a producing or proximate cause of plaintiffs' injuries and damages.

B. <u>Strict Liability – Failure to Warn</u>

5.06 In 2000 and thereafter, defendant failed to update its package inserts to include new class labeling regarding breast cancer risk, as the FDA instructed defendant and all other HRT

manufacturers to do. The FDA's new language to be inserted in all HRT labels warned that the addition of synthetic progestins, including MPA, to estrogen for HRT poses a higher risk of breast cancer than estrogen alone. Defendant's failure to strengthen its label to include these class-wide warnings makes it liable for failure to adequately warn under Utah's strict liability statute. No federal statute or regulation prohibited defendant from adopting the FDA-imposed class labeling for all HRT products.

5.07 In 2000 and thereafter, defendant failed to send "dear doctor" letters notifying physicians of the FDA's new class labeling for all HRT products, which warned that the addition of synthetic progestins, including MPA, to estrogen for HRT poses a higher risk of breast cancer than estrogen alone. Defendant's failure to notify physicians in this manner makes it liable for failure to adequately warn under California law. No federal statute or federal regulation prohibited defendant from conveying this information to physicians in the form of a "dear doctor" letter or similar communication.

5.08 The defect in defendant's label was a producing or proximate cause of plaintiffs' injuries and damages.

C. <u>Strict Liability – Design Defect</u>

5.09 Defendants manufactured, sold, and supplied their generic drug MPA, almost exclusively for use in combination hormone replacement therapy, and defendants were in the business of doing so. During plaintiff's use of defendants' MPA, defendants placed these drugs into the stream of commerce. Defendants' drugs were expected to, and did, reach plaintiff, who ingested defendants' MPA pills, without substantial change in their condition.

5.12 Under California law, a product may be defectively designed if the product did not perform as safely as an ordinary consumer would expect when used in an intended and reasonably

foreseeable manner and/or whether, on balance, the benefits of the challenged design outweighed the risk of danger inherent in the design. At the time the hormone replacement therapy drugs left defendants' hands, they were in a condition not contemplated by plaintiff and were unreasonably dangerous to her. Defendant's MPA drugs were dangerous to an extent beyond that which would be contemplated by the ordinary consumer in the following particulars:

a) MPA was known to have much more potent and different biological effects in the breast than progesterone;

b) Increasingly, published medical literature revealed that combination hormone replacement therapy using synthetic progestins such as MPA posed an unreasonable risk of breast cancer.

5.13 From the above facts, an ordinary consumer could find that the risks of defendants' MPA drug outweighed its utility, making it unreasonably and dangerously defective to plaintiff.

5.14 As a direct and proximate result of defendants' conduct, plaintiff suffered the injuries and damages claimed herein.

D. <u>Loss of Consortium</u>

5.15 At all times relevant hereto, Plaintiffs were married and were and now are husband and wife.

5.16 Prior to the negligence and wrongful conduct of the Defendants, and each of them, as set forth above, Plaintiff Irene Anderson was able to and did perform her normal and typical duties as a wife. Subsequent to the severe and disabling injuries suffered by Plaintiff Irene Anderson as a result of said negligence and wrongful conduct, as described above, and as a direct and legal result of the injuries caused thereby, as described above, she has been unable to perform her normal and typical duties as a wife. As a direct and legal result of Plaintiff Irene Anderson's inability to perform

her duties, Plaintiff Kenneth Anderson has suffered a loss of consortium as defined by law, including the loss of his wife's physical assistance in the operation and maintenance of their home, and he has further been deprived of and will in the future be deprived of his wife's comfort, society, solace and support. By reason thereof, Plaintiff Kenneth Anderson has been deprived of Plaintiff Irene Anderson's necessary duties as a wife, all to his further damage in a sum which will be set forth according to proof at trial. Plaintiff Kenneth Anderson is informed and believes, and based thereon alleges, that the injuries sustained by Plaintiff Irene Anderson will result in some permanent deprivation of her work and services as a wife, all to his further damage.

5.17 As an actual, legal, and direct result of the negligence of the Defendant, Plaintiff Kenneth Anderson has suffered damage.

VI. DAMAGES

6.01 The conduct of Defendant as specifically identified above with respect to Plaintiffs was a proximate and producing cause of substantial and permanent injuries and damages to Plaintiffs. As a result of this conduct by the Defendant, Plaintiffs suffered severe and permanent physical, mental, and emotional injuries. Plaintiffs seek all damages to which Plaintiff is entitled, both at law and in equity, from Defendant. Plaintiffs seek recovery for past and future medical expenses, lost wages and lost earning capacity, physical pain and mental anguish, disfigurement and physical impairment. Plaintiffs also seek attorneys' fees and expenses incurred in litigating this cause of action, along with exemplary damages.

6.02 Plaintiffs hereby request a jury trial.

FOR THESE REASONS, Plaintiff requests that upon final trial Plaintiff have judgment against the Defendants for Plaintiff's damages as set forth above, for attorneys' fees and expenses,

for exemplary damages, for pre- and post-judgment interest at the maximum rate allowed by law, for costs of court, and for such other and further relief to which Plaintiffs may be justly entitled.

Respectfully submitted,

/s/Ellen A. Presby
LES WEISBROD
Arkansas Bar No. 2005301
Texas State Bar No. 21104900
ELLEN A. PRESBY
Texas State Bar No. 16249600
MILLER WEISBROD, LLP
11551 Forest Central Drive, Suite 300
Dallas, TX 75243
(214) 987-0005 Telephone
(214) 987-2545 Facsimile
Email: lweisbrod@millerweisbrod.com

LEAD COUNSEL FOR PLAINTIFF

CERTIFICATE OF SERVICE

I, Ellen A. Presby, hereby certify that on this 1st day of October, 2012, I have electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which shall send notification of such filing to all counsel of record.

/s/Ellen A. Presby
Ellen A. Presby